IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JOHN COLEMAN, **Plaintiff,** **vs.** **MEDTRONIC, INC., "JOHN DOE 1-10", and "ABC CORP 1-10" (the last two being fictitious designations),** **Defendants.**	**CASE NO.: 2:21-cv-08064** **COMPLAINT AND JURY DEMAND**

INTRODUCTION

1. Plaintiff JOHN COLEMAN (hereinafter, "Plaintiff") residing in Cliffside Park, County of Bergen, and State of New Jersey suffered injuries as the result of the implantation of a defective double ventricular pacemaker branded, designed, manufactured, marketed, processed, distributed and/or sold by Defendants. This pacemaker was defective, dangerous, adulterated, and was culpably misrepresented as safe and/or healthy and/or did not conform to appropriate federal statutes and regulations, along with their parallel state counterparts.

JURISDICTION AND VENUE

2. This Court has diversity jurisdiction pursuant to 28 U.S.C. § 1332(a) because:

a. The amount in controversy exceeds the sum or value of $75,000, exclusive of interests and costs; and

b. Complete diversity exists between the Plaintiff and the named Defendants because Plaintiff is a citizen of the State of New Jersey, and—as is set forth in more detail in the

paragraphs that follow—Defendant MEDTRONIC, INC. (hereinafter, "Medtronic") is a citizen of the State of Minnesota.

3. Personal jurisdiction over the Defendants is proper because they have done and continue to do business in the State of New Jersey, with the claims asserted herein arising from such business; and they have committed the tortious acts which are the subject of this Complaint in New Jersey.

4. Venue in this district is proper for the same reasons and because Plaintiff suffered injury as a result of Defendants' acts in this District, and Defendants have intentionally availed themselves of the laws and markets of this District.

PARTIES

5. At all times relevant hereto, Plaintiff is an individual residing at 39 Lawton Ave, Cliffside Park, New Jersey.

6. At all times relevant hereto, Medtronic is a Corporation organized under the laws of the state of Minnesota, with a primary business address at 710 Medtronic Parkway, Minneapolis, Minnesota. Medtronic is the manufacturer and distributor of the double ventricular pacemaker implanted into the Plaintiff at issue in this complaint, as set forth in greater detail below.

7. "JOHN DOE 1-10", and "ABC CORP. 1-10" are fictitious designations used to identify other individuals and/or entities who may have been involved in the manufacture, sale, distribution and marketing of the double ventricular pacemaker implanted into the Plaintiff at issue in this complaint, either in their own individual capacity, or as agents and/or subsidiaries of Medtronic, who have not yet been identified despite the good faith efforts of Plaintiff and his counsel to do so.

OPERATIVE FACTS

8. Plaintiff repeats and restates the allegations of all preceding paragraphs as if fully set forth herein.

9. On or around August 11, 2017, Plaintiff was implanted with a Medtronic double ventricular pacemaker, Model number A2DRO1, Serial number PVY472602H, Model number 383069, Serial number LFF116299V and Model number 5076-52, Serial number PJN4627260 (hereinafter referred to as "the Subject Pacemaker").

10. The Subject Pacemaker was manufactured, marketed, advertised, and sold by Defendants Medtronic, "JOHN DOE 1-10", and/or "ABC CORP. 1-10" (hereinafter collectively referred to as "the Defendants").

11. The Subject Pacemaker was implanted pursuant to normal procedures and was used in the matter for which it was intended.

12. Post-implantation, Plaintiff underwent regular checks of the Subject Pacemaker performed by both a doctor and with a representative of the Defendants present to make sure the device was in working order.

13. On March 31, 2019, the Plaintiff underwent just such an examination, and a Representative of the Defendants interrogated the Subject Pacemaker.

14. That interrogation found the Subject Pacemaker to be functioning normally.

15. However, on April 6, 2019, plaintiff began suffering from presyncope, and went to his doctor again.

16. On that date, Plaintiff's doctor interrogated the Subject Pacemaker, and found that it was suffering from a malfunction which caused it to have an abnormally high stimulation threshold on the right ventricle side.

17. As a result of this malfunction, the Subject Pacemaker failed and plaintiff was forced to undergo emergency surgery to replace the Subject Pacemaker on April 8, 2019, resulting in personal injuries to the Plaintiff.

18. The Subject Pacemaker is a Class III device subject to Pre-market Approval (hereinafter, "PMA") under the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (hereinafter collectively referred to as "the MDA").

19. The Subject Pacemaker received PMA from the Food and Drug Administration (hereinafter, "FDA") on or around February 13, 2013.

COUNT ONE
PARALLEL CLAIM FOR PRODUCT LIABILITY UNDER THE MEDICAL DEVICE AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE NEW JERSEY PRODUCTS LIABILITY ACT

20. Plaintiff repeats and restates the allegations of all preceding paragraphs as if fully set forth herein.

21. Under the MDA, all class III devices—like the Subject Pacemaker—are required and are subject to the PMA process under the MDA.

22. Once PMA has been granted by the FDA, the manufacturer is forbidden from making, without FDA permission, any changes in design specifications, manufacturing processes, labeling, or any other attributes that would affect safety or effectiveness.

23. Upon information and belief, the defect in the Subject Pacemaker described in ¶¶ 8-19 above was the result of a negligent and/or reckless and/or knowing and/or intentional deviation

by the Defendants from the design specifications, manufacturing processes, labeling, and/or other attribute affecting the safety or effectiveness for the Subject Pacemaker previously approved by the FDA.

24. Upon information and belief, the Defendants' deviation from the design specifications, manufacturing processes, labeling, and/or other attribute affecting the safety or effectiveness for the Subject Pacemaker was not approved by the FDA.

25. Upon information and belief, the Defendants did not inform the FDA regarding their deviation from the design specifications, manufacturing processes, labeling, and/or other attribute affecting the safety or effectiveness for the Subject Pacemaker.

26. This unapproved deviation from the design specifications, manufacturing processes, labeling, and/or other attribute affecting the safety or effectiveness for the Subject Pacemaker constitutes a violation of the MDA and its attendant regulations.

27. By deviating from the design specifications, manufacturing processes, labeling, and/or other attribute affecting the safety or effectiveness for the Subject Pacemaker, the Defendants also breached their duty under the New Jersey Products Liability Law (hereinafter, "PLA") by:

a. Designing, manufacturing, assembling, supplying, installing, maintaining, inspecting, distributing, repairing and/or selling the Subject Pacemaker in a condition inherently dangerous for its intended use; and/or

b. Failing to take due care in the designing, manufacturing, assembling, supplying, installing, maintaining, inspecting, distributing, repairing and/or selling the Subject Pacemaker, resulting in the dangerous defects set forth above.

28. As a direct, proximate and reasonably foreseeable result of Defendants' violation of their duties under the MDA and the PLA, Plaintiff sustained serious and chronic injuries and was and

will be hindered and prevented from attending to his usual duties and has lost and will lose in the future economic damages; has suffered great pain and anguish.

WHEREFORE, Plaintiff, JOHN COLEMAN demands judgment against Defendants, MEDTRONIC, INC., "JOHN DOE 1-10) and/or "ABC CORP" 1-10 (the last two being fictitious designations), jointly, severally, and/or jointly and severally, for damages, interest, costs of suit, and such other relief as the Court deems necessary and proper.

COUNT TWO
DERIVATIVE CLAIM FOR PUNTITIVE DAMAGES

29. Plaintiff repeats and restates the allegations of all preceding paragraphs as if fully set forth herein.

30. Defendants knew that their products were defective but continued to design, manufacture, market and sell its products so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm.

31. The Defendants intentionally concealed or misrepresented facts known to it regarding the defective design and or manufacture of its products.

32. The Defendants failed to provide warnings to consumers about the risks of the design and/or manufacture of its products.

33. The Defendants' aforementioned conduct was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish defendants and deter them from similar conduct in the future. Defendants continue to promote its products without warnings and downplaying any risks.

WHEREFORE, Plaintiff, JOHN COLEMAN demands judgment against Defendants, MEDTRONIC, INC., "JOHN DOE 1-10" and/or "ABC CORP 1-10" (the last two being fictitious designations), jointly, severally, and/or jointly and severally, for damages, interest, costs of suit, and such other relief as the Court deems necessary and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

CERTIFICATION

I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

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